Abbott's Absorb™, the First Fully Dissolving Heart Stent, Earns Positive Review by FDA Advisory Committee

- Panel of Independent Experts Reviewed Clinical Data Supporting the Safety and Efficacy of the Absorb Device Compared to the Market-Leading Metallic Drug Eluting Stent

- Currently Available in More Than 100 Countries, the Absorb Bioresorbable Stent Has Been Used to Treat More Than 125,000 People Worldwide for Coronary Artery Disease[1]

WASHINGTON, March 15, 2016 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that an independent panel of experts convened by the U.S. Food and Drug Administration (FDA) voted 9 to 0, with one abstention, that the benefits of Abbott's Absorb fully bioresorbable drug eluting coronary stent outweigh the risks.

Absorb is a first-of-its-kind bioresorbable device for the treatment of coronary artery disease, which affects millions of adults nationwide and remains a leading cause of death despite decades of therapeutic advances. While most stents are made of metal, Abbott's Absorb stent is made of a naturally dissolvable material. Absorb dissolves completely after 2 to 3 years, once it has done its job of keeping a clogged artery open and promoting healing of the artery. By contrast, metal stents are permanent implants that restrict vessel motion by caging the artery for the life of the individual treated.

"Fully dissolvable devices represent a transformative advance in the treatment of coronary artery blockages," said Charles Simonton, M.D., FACC, FSCAI, chief medical officer and divisional vice president of medical affairs for Abbott's vascular business. "The unique benefit of Absorb is that it opens the blockage like a metallic stent, but then goes away over time, allowing the artery to return to a more natural state. That makes the Absorb stent a very attractive option for many patients who don't want permanent implants inside their arteries for the rest of their lives. We thank the members of the panel for their thorough review of the data, and we look forward to continuing discussions with the FDA on our submission for approval of this device in the U.S."

The FDA panel also voted on the device's safety and efficacy as a treatment for coronary artery disease. On the question of whether there is reasonable assurance that the device is safe, the vote was 9 to 1 in favor. On the separate question of whether there is reasonable assurance that the device is efficacious, the vote was 10 to 0 in favor.

The FDA advisory committee panel reviewed data from multiple studies of the Absorb dissolving stent, including ABSORB III, a company-sponsored U.S. clinical trial involving approximately 2,000 people that found the investigational device to be comparable to the market-leading metallic drug-eluting stent, Abbott's Xience™ drug eluting stent. At one year in ABSORB III, patients who received an Absorb dissolving stent had experienced comparable rates of specific adverse events—including heart disease-related death, heart attacks attributed to the stented artery and repeat procedures (collectively termed target lesion failure)—as compared to patients who received the Xience stent.

"In multiple randomized clinical trials, the Absorb bioresorbable vascular scaffold has demonstrated comparable outcomes to the leading permanent metallic stent. As a first-in-kind device with novel properties, including complete dissolution and natural restoration of vessel function, this is a remarkable achievement," said Gregg W. Stone, M.D., FACC, FSCAI, director, cardiovascular research and education, Center for Interventional Vascular Therapy, Columbia University Medical Center, New York-Presbyterian Hospital and the chairman of the ABSORB clinical trial program. "The available evidence supports an important role for this innovative device in the treatment of coronary artery disease."

Abbott submitted its pre-market approval (PMA) application for the Absorb dissolving stent in mid-2015 to the FDA, which convened today's advisory committee panel for expert advice on the device's clinical safety, efficacy, risk and benefit. The FDA routinely seeks input from advisory committees, especially for first-in-kind medical devices. The FDA's decision on Abbott's PMA for the Absorb dissolving stent is expected later this year.

About Abbott:
At Abbott, we're committed to helping you live your best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world—in nutrition, diagnostics, medical devices and branded generic pharmaceuticals—that create more possibilities for more people at all stages of life. Today, 74,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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[1] Based on worldwide device utilization rate. Data on file at Abbott Vascular .

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